

REMARKS

The Final Office Action of October 20, 2005 has been reviewed and the comments therein were carefully considered. Claims 1-5, 7-9, and 40-49 are currently pending in the present application. Claims 1-5, 7-9, and 40-49 are rejected. No new matter has been introduced into the application.

Rejections under 35 USC §102

Claim 9 is rejected under 35 USC §102(b) as being anticipated by Fischell, WO/03218. Applicants respectfully traverse the rejection.

Fischell discloses an implantable programmable infusion pump for infusing medication in accordance with programmable prescription parameters and dosage limits. (Page 2, lines 24-27). The device consists of a medical programming unit (MPU) and a patient programming unit (PPU). (Page 3, lines 10-12). The MPU allows a physician to program basal and supplemental prescription schedules and dosage limits based on an individual patient's physiology. (Page 3, lines 14-17; page 5, lines 16-18). The PPU allows a patient to self-medicate (page 3, lines 12-14), but is limited because "a patient can merely choose to deliver a full or half basal rate, select one of the pre-programmed supplemental prescription schedules, inhibit pump activity, or countermand previous directives." (Page 3, lines 20-25).

With regard to claim 9, Fischell does not disclose, teach, or suggest the creation of a personalized therapy program "based on patient activity." (Emphasis added). Fischell is concerned with allowing a patient to select pre-programmed prescription schedules and to choose either a half or full basal rate. Although the dosage limits are based on a particular patient's physiology, they are not based on patient activity.

Support for the claimed feature of “at least one personalized drug therapy program based on patient activity” may be found in the Specification on Page 12, lines 10-22, which states:

Once the patient has created a personalized therapy program 190, a Save function can be selected. . . . For example, the user could label the just created personalized therapy program 190 a “Sleep” program. . . . The patient could repeat the above steps to create other personalized therapy programs 190, for example programs such as “Running”, “Eating”, “Sitting”, “Exercising” and others.

As specified above, the creation of personalized therapy programs by patients may be based on a patient’s particular activity at a specified moment in time. Such patient activities may include sleeping, running, eating, sitting, or exercising. Fischell does not disclose, teach, or suggest at least this claimed feature.

In addition, Fischell does not disclose, teach, or suggest “creating by the patient at least one personalized therapy program from the accessed preset clinician therapy programs, the at least one personalized therapy program based on patient activity” (Emphasis added). In Fischell, “[t]he PPU [Patient Programming Unit] can be used by the patient to: (1) request delivery of one of eight supplemental prescription schedules which were pre-programmed by the physician; (2) select half or full basal rate delivery of the pre-programmed basal prescription schedule; (3) inhibit pump operation for 1-hour periods; and (4) countermand the current medication directive.” (Page 11, lines 23-30). None of these four patient options allows the patient to create and store a personalized therapy program like Applicant’s claimed invention.

Therefore, for at least these reasons, it is respectfully submitted that claim 9 is patently distinct over Fischell.

Rejections under 35 USC §103

Claims 1-5, 7-9 and 40-49 are rejected under 35 USC §103(a) as being unpatentable over Snell, U.S. Patent No. 5,456,691 in view of Fischell, WO/03218 or vice versa. Applicants respectfully traverse the rejection.

Snell discloses a programmer in which a control program for an implantable medical device is constructed from program modules that are selected by a physician. (Abstract). The modules may be individually loaded into the implantable medical device or may be combined into a single program, without necessitating an increase in the memory capacity of the implantable device. (Col. 2, lines 7-10). In Snell, a physician selects the software or functions (e.g., cardioversion or defibrillation) that the patient is expected to require. If the software or function is not loaded, the device will be incapable of performing the function.

With regards to independent claims 1 and 40, neither Snell nor Fischell discloses, teaches, or suggests “creating by the patient at least one personalized drug therapy program from the accessed preset clinician drug therapy programs, the at least one personalized drug therapy program based on patient activity.” (Emphasis Added). In Snell, only a physician or trained specialist can construct control programs from program modules. The patient is not allowed to create or store any programs based on patient activity. Also as discussed above with respect to Fischell, the four patient options do not allow the patient to create and store a personalized therapy program as claimed in Applicants invention. In contrast, applicant’s claimed invention “allows a patient to . . . modify the stored therapy programs to accommodate his/her particular lifestyle, thereby creating and storing personalized therapy programs.” (Specification on Page 5, lines 20-23).

Therefore, for at least these reasons, it is respectfully submitted that independent claims 1 and 40 are patentable over Snell in view of Fischell or vice versa. Dependent claims 2-5, 7-8, and 41-49 which ultimately depend from one of independent claims 1 or 40 are allowable for at least the same reason as the independent claim from which they ultimately depend.

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

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Respectfully submitted,
By: William J. Allen 51,393
William J. Allen
Registration No. 51,393
BANNER & WITCOFF, LTD.
10 South Wacker Drive, #3000
Chicago, IL 60606
Telephone: 312-463-5000
Facsimile: 312-463-5001